K010685

APR - 2 2001

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, Indiana 46581-0708 219-267-6131
Contact Person:	Stephen McKelvey Manager, Regulatory Affairs
Telephone:	219/372-4944
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Date:	March 6, 2001
Trade Name:	Miller/Galante Precoat Unicompartmental Knee System (8 mm Articular Surface)
Common Name:	Unicompartmental Knee
Classification Name and Reference:	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis, (888.3520)
Predicate Devices:	The predicate devices for the Miller/Galante Precoat Unicompartmental Knee System (8 mm articular surface) are the Miller/Galante Precoat Unicompartmental Knee System, K880155 (cleared 8/3/98) and the Miller/Galante Precoat Unicompartmental Knee System (Ultrapek spring), K942263 (cleared 7/11/95).
Device Description:	The 8 mm articular surface component is manufactured of machined Ultra-High Molecular-Weight (UHMWPE) polyethylene and is identical to the predicate devices.
Intended Use:	The Miller/Galante Precoat Unicompartmental Knee is intended for patients with painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis, previous tibial condyle or plateau fractures with loss of anatomy or function, valgus or varus deformities, and for revision of previous arthroplasty procedures.

Comparison to Predicate Devices:	The Miller/Galante Precoat Unicompartmental Knee System (8 mm articular surface) is identical to the predicate devices. The modification (line extension) does not change the intended use or the fundamental scientific technology. It is packaged and sterilized using the same materials and processes.
Performance Data:	Performance testing completed as part of the design assurance procedure for the Miller/ Galante Precoat Unicompartmental Knee System (K880155) and FMEA demonstrated that this device (including the 8 mm articular surface) is safe and effective and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2001

Mr. Stephen H. McKelvey
Manager, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K010685
Trade Name: Miller/Galante Precoat Unicompartmental Knee System (8 mm Artiular Surface), Line Extension
Regulatory Class: II
Product Code: HSX
Dated: March 6, 2001
Received: March 8, 2001

Dear Mr. McKelvey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K010685

Device Name:

Miller/Galante Precoat Unicompartmental Knee System (8 mm Articular Surface)

Indications for Use:

The Miller/Galante Unicompartmental Knee is intended for patients with painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis, previous tibial condyle or plateau fractures with loss of anatomy or function, valgus or varus deformities, and for revision of previous arthroplasty procedures.

for Mark N Milhenson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010685

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No
(Optional Format 1-2-96)